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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/454,684	12/03/1999	PETER PROBST	210121.469C4	4092

500 7590 09/21/2004

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/21/2004

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/454,684

Applicant(s)

PROBST ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 1-2, 7-10, 13, 15, 17A, 18, 20, 22(a), 23-25.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 7-10, 13, 15, 17A, 18, 20, 22(a) and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4215</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-6, 11-12, 14, 16, 17(b-c), 19, 21, 22(b-c) and 26-66.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, SEQ ID NO:180 in the reply filed on August 6, 2001 is acknowledged. Claims 3-6, 11-12, 14, 16, 17(b-c), 19, 21, 22(b-c), and 26-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 6, 2001.

It is noted that claims 64-66 were included in the elected group, however claims 64-66 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Each sequence listed in claims 64-66 is directed to or involves the use of sequences which are recognized in the art as being distinct from one another because of they are structurally distinct molecules and is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, the disclosed polynucleotides of claim 1 do not necessarily encode a particular polypeptide found in claims 64-66. Furthermore, it is clear that the polynucleotides of claim 1 can be used to make a materially different polypeptide than the polypeptides found in claims 64-66. For example, the claimed nucleic acids may encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO. 180.

Furthermore, searching the inventions of patentable distinct inventions encompassed by SEQ ID NO:18, 19, 31, 39, 93-96, 100-102, 106,108, 138-140, 158, 167, 168, 246, 247 and 254-256 together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions have a separate status in the art. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes possible polypeptides as explained above; furthermore, a search of the nucleic acid molecules would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptides. As such, it would be burdensome to search the inventions of drawn to additional polypeptides comprising SEQ ID NO: 18,19, 31, 39, 93-96, 100-102, 106,108, 138-140, 158, 167, 168, 246, 247 and 254-256 together.

Since applicant has elected the claims of Group I, claims 1-2, 7-10, 13, 15, 17A), 18, 20, 22(a) and 23-25 will be considered in this action. Accordingly, claims 64-66 are

withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-2, 7-10, 13, 15, 17A), 18, 20, 22(a) and 23-25 are under consideration in this office action.

Priority

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application.

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The benefit of the earlier filing date under 35 U.S.C. 120 of the parent application Serial No. 09/410,568, 09/288,594, 09/208,277 has been denied for claims 1-2, 7-10, 13, 15, 17A), 18, 20, 22(a), and 23-25 for the instant application. The claims in the instant continuation application recites a feature, i.e., an amino acid sequence SEQ ID NO:180

which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent application. This feature has been first introduced and adequately supported in the instant application and thus such claims are entitled only to the filing date of the instant application; In re Von Lagenhoven , 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972) and Chromalloy American Corp. v. Alloy Surfaces Co ., Inc ., 339 F. Supp. 859, 874, 173 USPQ 295, 306 (D. Del. 1972).

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
5. The disclosure is objected to because of the following informalities: page 92 refers to Table II, however there is no Table present. Appropriate correction is required.

Claim Objections

6. Claims 23-25 are objected to because of the following informalities: Claims 23-25 are dependent upon non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 7-10, 13, 15, 17A), 18, 20, 22(a) and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-2, 7-10, 13, 15, 17A), 18, 20, 22(a) and 23-25 are drawn to an isolated polypeptide comprising an immunogenic portion of a *Chlamydia* antigen wherein said antigen comprises an amino acid sequence (SEQ ID NO:180) encoded by polynucleotide selected from the group consisting of a) the sequence recited in SEQ ID NO:174; b) sequences complementary to a sequence of (a); and c) polynucleotide sequences that hybridize to a sequence of (a) or (b) under moderately stringent conditions. The dependant claims are drawn to a fusion protein; a pharmaceutical composition; a vaccine; and a method of inducing protective immunity in a patient comprising the administration of the composition or vaccine. Thus the claims drawn to an isolated polypeptide comprising an immunogenic portion of a *Chlamydia* antigen wherein said antigen comprises an amino acid sequence encoded by polynucleotide selected from the group consisting of sequences complementary to a sequence of (a); and c) polynucleotide sequences that hybridize to a sequence of (a) or (b) under moderately stringent conditions fails to meet the written description requirements.

The claims drawn to the amino acid sequences fail to recite any associated function. Without an associated function, the claims fail to limit the sequences encompassed by applicants' claims. It is noted that there is no requirement that the polypeptides have an ascertainable activity associated with *Chlamydia*. Furthermore any variant or mutant that has similar sequence identity yet has a different function is also encompassed by the claims. Moreover, the specification teaches polypeptides are believed to be of biological relevance in generating a protective immune response to a Chlamydial infection and the inventors suggest that the *pmp* genes may be outer membrane proteins and concluded that the proteins may be potential immunological targets. See page 67 of the instant specification. Therefore, the specification lacks adequate support for this conclusion and claim. Thus, the structure of sequences having sufficient activity have not been defined and thus broadens the scope of the invention to encompass the amino acid sequences. Furthermore, the structure of sequences having sufficient activity has been not described by the instant specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC

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112 is severable from its enablement provision (see page 115). The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus, including a functional activity.

Currently the instant claims which lack a function of the amino acid sequences are insufficient to support the claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The claims and specification are also drawn to sequences complementary to a sequence of claim 1(a); and polynucleotide sequences that hybridize to a sequence of claim 1(a) or (b) under moderately stringent conditions however this description fails to provide the identity or structure of this isolated polypeptide sequence. The specification does not state the identity of such sequences or any structural characteristics of any other nucleic acid sequence that has the claimed characteristics of being complementary or capable of hybridizing. Moreover, there is evidence that other sequences have not yet been identified therefore; applicants' vague description of isolated sequences has not been adequately described. In view of the lack of evidence, it is apparent that Applicants were not in possession of additional sequences that are complementary to SEQ ID NO:174 or 180 or sequences that hybridize to SEQ ID NO:174 or 180, at the time of filing the instant application.

A skilled artisan cannot envision the detailed structure of the isolated nucleic acid sequence which will encode polypeptides that are complementary to a sequence of claim 1(a); and polynucleotides that hybridize to said sequence under moderately stringent conditions, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The polypeptide structure is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. The activity or characteristics distinguish the polypeptide only by what it does, i.e., hybridize, which is a purely functional distinction. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims describe an isolated polypeptide encoded a polynucleotide having a complementary or hybridizing function, however this description does not describe the claimed polypeptide itself.

See also, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states

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that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Thus, in the absence of sequence information of the encoded polypeptide which is complementary or hybridizable, a polypeptide described only by its complementary or hybridizing activity fails to meet the written description requirements.

Instant claims 13, 15, 17A), 18, 20, 22(a), 23-25 are drawn to pharmaceutical compositions, vaccines and methods of inducing protective immunity comprising a polypeptide with sequences complementary to a sequence of claim 1(a); and polynucleotide sequences that hybridize to a sequence of claim 1(a) or (b) under moderately stringent conditions. However, because the polypeptides do not have to be fully complementary and only need to hybridize under moderate conditions the claims encompass many unrelated polypeptides along with polypeptides that may not be able to function to provide protective immunity. For instance, selective point mutations to one key antigen residue could eliminate the ability of an antibody to recognize this altered antigen and eliminate such polypeptides from providing protective immunity. If the range of decreased binding ability after single point mutation of a protein antigen varies, one could expect point mutations in the protein antigen to cause varying degrees of loss of protection, depending on the relative importance to the binding interaction of the altered residue. Alternatively, the combined effects of multiple changes in an antigenic determinant could again result in loss of protection. A protein having multiple antigenic sites, multiple point mutations or accumulated point mutations at key residues

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could create a new antigen that is precipitously or progressively unrecognizable by any antibodies in the polyclonal pool and fail to provide protective immunity. Thus, polypeptides of different levels of homology may not induce antibody that would be effective against a Chlamydia infection.

Furthermore, the specification fails to provide an enabling disclosure for the use of any amino acid encoding polypeptides that are complementary to a sequence of claim 1(a); and polynucleotide sequences that hybridize to a sequence of claim 1(a) or (b) under moderately stringent conditions and that when introduced into a host would induce an immune response against the encoded polypeptide. Applicants' have provided no guidance to enable one of skill in the art as to how determine, without undue experimentation, the effects of different amino acid substitutions and the nature and extent of the changes that can be made. There is no requirement for the use of only conservation substitutions. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable amino acid sequences, one skilled in the art could not make or use the broadly claimed invention without undue experimentation.

Claims 18, 20, 22(a) and 23-25 are drawn to a vaccine and method of inducing protective immunity. The instant specification fails to describe any experiments that show that polypeptides which are believed to be of biological relevance in generating a protective immune response to a Chlamydial infection would be effective in protecting a human or other animal against an infection. The term "vaccine" encompasses the ability

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of the specific antigen to induce protective immunity to an infection or disease induction. The vaccine art is highly unpredictable and the instant specification fails to disclose any information that the polypeptides would provide protective immunity to any patient against any type of infection. There is no requirement that the vaccine treat only *Chlamydia* infections. The specification fails to teach any immunological experiments that demonstrate that the claimed vaccine is capable of mounting a protective immune response against an infection. There is no teaching of immunological experiments that teach that the claimed vaccine is capable of mounting an enhanced and effective immune response and more importantly, there are no challenge experiments within the specification that demonstrate that an animal immunized with the polynucleotides encoding the recited polypeptides would be protected from either a *Chlamydial* or any other type of bacterial infection. More importantly, there are no challenge experiments to demonstrate that an animal immunized with the vaccine would be protected from each and every type of infection. It is unclear that one of skill in the art could follow these general guidelines and achieve immunization using the vaccine. The specification does not provide substantive evidence that the claimed vaccine is capable of inducing protective immunity against any type of infection and/or disease.

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit *in vivo* protective immunity. Ellis exemplifies this problem in the recitation that "the key to the problem (of

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vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies" (page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al., wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2).

Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy. The specification fails to teach the identity a vaccine with the claimed characteristics. Furthermore, the specification fails to provide an adequate teaching of the vaccine, thus a skilled artisan would be required to de novo locate, identify and characterize the claimed vaccine with the claimed abilities. Accordingly, this would require undue experimentation given the fact that the specification is completely lacking in teachings as to vaccines with the broadly claimed protection characteristics. Thus, the art indicates that it would require undue experimentation to formulate and use a successful vaccine comprised of the claimed polypeptides without the prior demonstration of vaccine efficacy.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-2, 7-10, 13, 15, 17A), 18, 20, 22(a) and 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, credible or substantial asserted utility or a well-established utility.

Applicants have asserted several utilities for the claimed polypeptides and polynucleotides encoding such polypeptides molecules comprising SEQ ID NO: 174 and 180, including derivatives and variants of said sequences. The asserted uses include therapeutics, diagnostic tools, pharmaceutical compositions and vaccines for the prevention of diseases associated with expression of these sequences, pages 3-5. However, these asserted utilities are neither specific nor substantial. The broadly claimed polynucleotide is based on SEQ ID NO: 174 which allegedly encode a polypeptide having the sequence designated as SEQ ID NO: 180 also referred to as the *pmpB* gene. The inventors performed a homology search and determined that the instant sequences shared homology to various polymorphic membrane proteins (*pmp*). The inventors state that the proteins expressed from the *pmp* genes are believed to be of biological relevance in generating a protective immune response to a Chlamydial infection. The inventors suggest that the *pmp* genes may be outer membrane proteins and based on those results the inventors concluded that the genes are potential immunological targets. See page 67.

Generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick et al. (Trends in Biotech. 18:34-39, January 2000) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and

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is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Similarly, Bork (Genome Research 10:398-400, 2000) states that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially p. 399). Such concerns are also echoed by Doerks et al. (Trends in Genetics 14:248-250, June 1998) who state that (1) functional information is only partially annotated in the database, ignoring multi functionality, resulting in under predictions of functionality of a new protein and (2) over predictions of functionality occur because structural similarity often does not necessarily coincide with functional similarity. Smith et al. (Nature Biotechnology 15:1222 and 1223, November 1997) remark that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. Brenner (Trends in Genetics 15 (4):132-133, April 1999) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, than most homologs must have different molecular and cellular functions. Bork et al. (Trends in Genetics 12(10):425-427, October 1996) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts. Finally, Bowie et al. (Science 247:1306-1310, March 16, 1990) state that determination of three-dimensional structures from primary amino acid sequence, and the subsequent

inference of detailed aspects of function from structure is extremely complex and unlikely to be solved in the near future (p. 1306). Thus, the specification fails to support the asserted credible, specific and substantial utility of gene activity. The specification does not disclose a correlation between any specific function and the claimed polypeptides and polynucleotides that encode those polypeptides. Information provided in the specification is not sufficient to establish that it plays a role in the function of the polypeptides.

Accordingly, those skilled in the art cannot rely on this information to implement the processes of treatment or diagnosis. Given the lack of any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form, thus the use of the claimed isolated polynucleotides and polypeptides is not credible, substantial or specific.

9. Claims 1-2, 7-10, 13, 15, 17A), 18, 20, 22(a) and 23-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Prior Art

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ratti (US Patent 5,629,167) teach the detection of antibodies

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against Chlamydia antigens. Stevens et al., teach the genome sequence of an obligate intracellular pathogen of humans.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines *JNH*
September 14, 2004

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